DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 11, 2016

NLT Spine, Ltd.
% John Smith, M.D., J.D.
Hogan Lovells US LLP
555 Thirteenth Street, N.W.
Washington, District of Columbia 20004

Re: K153786
Trade/Device Name: PROW FUSION-V
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: June 15, 2016
Received: June 15, 2016

Dear Dr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K153786

Device Name

PROW FUSION-V

Indications for Use *(Describe)*

PROW FUSION-V is an interbody fusion device intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).

PROW FUSION-V is to be filled with autogenous bone graft material. The device is intended to be used with supplemental fixation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

NLT SPINE's PROW FUSION-V

As required by 21 C.F.R. § 807.92

Sponsor:

NLT SPINE Ltd.
6 Yad Harutzim St.
Kfar-Saba
Israel 4464103

Contact Person:

Eti Zinger
VP Regulatory Affairs
NLT SPINE Ltd.
Tel: +972-3-6344514
Fax: +972-3-6341599
Eti.z@nlt-spine.com

Date Prepared: July 7, 2016

Name and Classification:

Name of Device:	PROW FUSION-V
Common or Usual Name:	Intervertebral body fusion device
Classification Name:	Intervertebral body fusion device
Classification:	21 CFR §880.3080
Product Code:	MAX
Class:	II

Primary Predicate Device:

Globus Medical, CALIBER Spacer (K123231)

Additional Predicate devices:

SpineSource, Inc. L-Varlock Lumbar Cage (K080537);
NuVasive CoRoent System (K141665)
Globus Medical, RISE Spacer (K113447)

Intended Use / Indications for Use

PROW FUSION-V is an interbody fusion device intended for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).

PROW FUSION-V is to be filled with autogenous bone graft material. The device is intended to be used with supplemental fixation.

Technological Characteristics

PROW FUSION-V is lumbar interbody fusion devices used to provide structural stability in skeletally mature individuals following discectomy. PROW FUSION-V is provided in different shapes to fit the anatomical needs of a wide variety of patients and can expand to the desired height or the desired lordosis.

Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to resist expulsion. The devices require the use of commercially available supplemental spinal fixation systems.

PROW FUSION-V is manufactured from titanium alloy per ASTM F136.

PROW FUSION-V is to be filled with autogenous bone graft material.

Performance Data

Mechanical testing consisting of static and dynamic compression, static and dynamic compression-shear according to ASTM F2077 and subsidence according to ASTM F2267 was conducted in accordance with "Class II Special Controls Guidance Document: Intervertebral Fusion Device", June 12, 2007 to demonstrate substantial equivalence to the predicate. Cadaveric study conducted to evaluate proper placement of the device, graft containment and no damage to the vertebral endplate. In addition, max expansion force and wear particle assessment testing were also performed.

Substantial Equivalence

PROW FUSION-V is similar to the predicates with respect to technical characteristics, performance and intended use. The information provided within this premarket notification supports substantial equivalence of the subject PROW FUSION-V to the predicate devices.